K000196

FEB 1 8 2000

Summary of 510(k) Safety and Effectiveness

January 20, 2000

1. General Information

Device Generic Name:	Enzyme Immunoassay, Myoglobin
Device Trade Name:	ACCESS® Myoglobin assay
Applicant's Name and Address:	Beckman Coulter, Inc. 1000 Lake Hazeltine Drive Chaska, MN 55318
Contact Person:	Jan Olsen

2. Predicate Device

Behring Diagnostics N Latex Myoglobin Reagents
Behringwerke AG
Marburg, Germany

3. Device Description

The ACCESS® Myoglobin assay is a paramagnetic-particle, chemiluminescent immunoassay for the quantitative determination of myoglobin levels in human serum or plasma (heparin and EDTA), using the ACCESS® Immunoassay System.

4. Comparison of Technological Characteristics

The ACCESS® Myoglobin Assay and the Behring N Latex Myoglobin test are for the measurement of Myoglobin in human serum. Both tests utilize the binding of myoglobin to specific antibodies. Both tests utilize light in their respective detection systems--the ACCESS® Myoglobin test measures light production from a chemiluminescent reaction using a luminometer, while the Behring N Latex Myoglobin test measures light scattering intensity using a nephelometer. The ACCESS® Myoglobin test is an enzyme immunoassay, while the Behring N Latex Myoglobin assay is a particle enhanced nephelometric assay. The ACCESS® Myoglobin Calibrators (six levels) are prepared from human heart myoglobin and a buffered BSA matrix, while the Behring N Latex Myoglobin Calibrator (single level from which dilutions are made) is prepared from human myoglobin and human serum-based matrix.

5. Summary of Studies

Precision studies: Within run imprecision ranges from 2.06 % CV (high human serum pool) to 3.69 % CV (low human serum pool). Between run imprecision ranges from 4.47% CV (high human serum pool) to 6.39 % CV (low human serum pool).
Spiking and Dilution Recovery: Linearity studies performed by diluting three human serum samples containing Myoglobin with Myoglobin Calibrator S0 (zero) gives an average recovery of 100 %.
Correlation: A comparison of serum Myoglobin values from 93 samples run in both the ACCESS® Myoglobin assay and the Behring N Latex Myoglobin test gives the following statistical data: $r = 0.998$ $y = 0.916x + 11.31$. A comparison of 51 paired serum and plasma (EDTA) samples run in the ACCESS® Myoglobin assay gives the following statistical data: $r = 0.999$, $y = 0.854x + 3.073$.
Analytical Sensitivity: The lowest detectable level of Myoglobin distinguishable from zero (Myoglobin Calibrator S0) with 95% confidence is 8.9 ng/ml.

6. Conclusion

The ACCESS® Myoglobin reagents when utilized with the ACCESS® Immunoassay Analyzer are substantially equivalent to another test currently in commercial distribution for the measurement of Myoglobin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 8 2000

Ms. Jan Olsen
Staff Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

Re: K000196
Trade Name: Access® Myoglobin Reagents
Regulatory Class: II
Product Code: DDR
Dated: January 20, 2000
Received: January 21, 2000

Dear Ms. Olsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000196

Device Name: Access® Myoglobin Reagents

Indications For Use:

The ACCESS® Myoglobin assay is a paramagnetic-particle, chemiluminescent immunoassay for the quantitative determination of Myoglobin levels in human serum or plasma, using the Access Immunoassay System. Measurement of Myoglobin aids in the rapid diagnosis of heart or renal disease.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000196

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)